Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Parawork Reduction of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Substitute to	or form 1449B	/PTO	Complete if Known		
	INFORMATI	ON DISCLO	SURE	Application Number	10/615,497	
STATEMENT BY APPLICANT				Filing Date	07/07/2003	•
				First Named Inventor	Doug Hui Huang	
				Group Art Unit	1632	
	(use as many s	sheets as ne	cessary)	Examiner Name		
Sheet	1	of	10	Attomey Docket Number	034827-1303	

U.S. PATENT DOCUMENTS						
		U.S. Patent	Document		Date of Publication of	Pages, Columns, Lines, Where Relevant
Examiner Initials*	Cite No. ¹	Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
DBJ	A1	5,648,482		Meyer	07-15-1997	
	A2	5,981,174		Wolf et al.	11-09-1999	
	A3	6,060,253		Gelboin et al.	05-09-2000	
DBJ	A4	6,183,963		Sinnett et al.	02-06-2001	
						× ×
				·		

				F(OREIGN PATENT DOCUMEN	TS		
Examiner Initials*	Cite No.1	Fo Office ³	oreign Patent D	Ocument Kind Code ⁵ (If known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
DBJ	A5	wo	00/66775		Sumitomo Pharmaceuticals			_
			·		(abstract only	y)		
								J

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	τ [¢]
DBJ	A6	Belpaire and Bogaert, Cytochrome P450: genetic polymorphism and drug interactions, Acta Clin Belg 51:254-60, 1996.	
DBJ	A7	Bertilsson and Dahl, Polymorphic drug oxidation: Relevance to the treatment of psychiatric disorders, CNS Drugs 5:200-223, 1996.	
DBJ	A8 -	Birgersdotter et al., Stereoselective genetically-determined interaction between chronic flecainide and quinidine in patients with arrhythmias, Brit J. Clin. Pharmacol. 33:275-280, 1992.	-
. DBJ	A9	Buchert and Woosley, Clinical implications of variable antiarrhythmic drug metabolism, Pharmacogenetics 2:2-11, 1992.	
		·	

	التكاليب كالترجيجين المستجرات		
Examiner Signature	/Diana B. Johannsen/	Date Considered	10/23/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Oraw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

MODIFIED PTO/SB/08 (08-00) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Respection Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449B/PTO INFORMATION DISCLOSURE **Application Number** 10/615,497 STATEMENT BY APPLICANT **Filing Date** 07/07/2003 Doug Hui Huang First Named Inventor 1632 **Group Art Unit** (use as many sheets as necessary) **Examiner Name** 2 10 034827-1303 Attorney Docket Number Sheet

NON PATENT LITERATURE DOCUMENTS						
Examiner Cite No. 1 DBJ A10		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.				
		Chauret et al., In Vitro Comparison of P450-Mediated Metabolic Activities in Human, Dog, Cat, and Horse, Drug Metabolism and Disposition 25:1130-1136, 1997				
	A11	Chen et al., CYP2D6 Genotype and the Incidence of Anal and Vulvar Cancer, Cancer Epidemiology, Biomarkers & Prevention 8:317-321, 1999				
	A12	Cholerton et al., Comparison of a novel thin-layer chromatogrphic-fluorescence detection method with a spectrofluorometric method for the determination of 7-hydroxycoumarin in human urine, J. Chromatogr. 575, 325-330, 1992				
	A13	Crespi and Miller, The use of heterologously expressed drug metabolizing enzymes—state of the art and prospects for the future, Pharmacology and Therapeutics 84:121-131, 1999				
	A14	Dahl et al., Ultrarapid hydroxylation of debrisoquine in a Swedish population. Analysis of the molecular genetic basis, J Pharmacol Exp Ther 274:516-20, 1995				
	A15	Daly et al., Nomenclature for human CYP2D6 alleles, Pharmacogenetics 6:193-201, 1996				
	A16	Daly, Molecular basis of polymorphic drug metabolism, J. Mol. Med. 73, 539-553, 1995				
\downarrow	A17	Dayer et al., Enzymatic basis of the debrisoquine/sparteine-type genetic polymorphism of drug oxidation. Characterization of bufuralol 1'-hydroxylation in liver microsomes of in vivo phenotyped carriers of the genetic deficiency, Biochem. Pharmacol. 36, 4145-4152, 1988				
DBJ A18		De Morais et al, "Identification of new genetic defect responsible for the polymorphism of (S)-Mephenytoin metabolism in Japanese." Mol. Pharmacol. 46: 594-598, 1994.				

Examiner Signature	/Diana B. Johannsen/	Date Considered	10/23/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE on Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Under the paperwork Re Substitute for form 1449B/PTO Complete if Known **Application Number** 10/615,497 INFORMATION DISCLOSURE 07/07/2003

STATEMENT BY APPLICANT Filing Date **First Named Inventor** Doug Hui Huang 1632 Group Art Unit (use as many sheets as necessary) **Examiner Name** 3 of 10 **Attorney Docket Number** 034827-1303 Sheet

		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite No.1 DBJ A19		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	۲
		Dolnik, DNA sequencing by capillary electrophoresis (review), J Biochem Biophys Methods 41:103-19, 1999	
	A20	Dovichi and Zhang, DNA sequencing by capillary array electrophoresis, Methods Mol Biol 167:225-39, 2001	
	A21	Dunning et al., A Systematic Review of Genetic Polymorphisms and Breast Cancer Risk, Cancer Epidemiology, Biomarkers & Prevention 8:843-854, 1999	, .
	A22	Eichelbaum & Gross, The genetic polymorphism of debrisoquine/sparteine metabolism – clinical aspects, Pharmac. Ther. 46:377-394, 1990	
	A23.	Evans et al., The genetic control of sparteine and debrisoquine metabolism in man with new methods of analysing bimodal distrubtions, J. Med. Genet 20, 321-329, 1983.	_
	A24	Fabian and Degtyarenko, The Directory of P450-containing Systems in 1996, Nucleic Acids Research 25:274-277, 1997	
\	A25	Fahy et al., Mutliplex fluorescence-based primer extension method for quantative mutation analysis of mitrochondrial DNA and its diagnostic application for Alzheimer's disease, Nucleic Acid Research 25:3102-3109, 1997	
DBJ	A26	Femandez-Salguero et al., A genetic polymorphism in coumarin 7-Hydroxylation: sequence of the human CYP2A genes and identification of variant CYP2A6 alleles, Am. J. Hum. Genet. 57, 651-660, 1995	

Examiner	/Diana B. Johannsen/	Date	10/23/2006
Signature		Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. *Applicant is to place a check mark here if English language

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Recipion Act of 1995 of persons are required to respond to a collection of information unless it contains a valid OMB control

number.	Substitute for	TOTHE THAT 9B			Complete if Known	
	INFORMATIO	N DISCLO	SURE	Application Number	10/615,497	
STATEMENT BY APPLICANT			ICANT	Filing Date	07/07/2003	· · · · · · · · · · · · · · · · · · ·
				First Named Inventor	Doug Hui Huang	
				Group Art Unit	1632	
	(use as many sh	eets as ne	cessary)	Examiner Name		
Sheet	4	of	10	Attorney Docket Number	034827-1303	

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т ⁶		
DBJ A27		Fischer et al., The antipsychotic clozapine is metabolized by the polymorphic human microsomal and recombinant cytochrome P450 2D6, J. Pharmacol. Exp. Ther. 260:1355-1360, 1992			
	A28	Fonne-Pfister and Meyer, Xenobiotic and endobiotic inhibitors of cytochrome P-450dbl function, the target of the debrisoquine/sparteine type polymorphism, Biochem. Pharmacol. 37:3829-35, 1988			
	A29	Gaedigk et al., Deletion of the entire cytochrome P450 CYP2D6 gene as a cause of impaired drug metabolism in poor metabolizers of the debrisoquine/sparteine polymorphism, Am. J. Hum. Genet. 48, 943-950, 1991			
	A30	Goldstein and deMorais, Biochemistry and molecular biology of the human CYP2C subfamily, Pharmacogenetics 4: 285-299, 1994.			
•	A31	Gonzalez & Gelboin, J., Role of human cytochrome P-450s in risk assessment and susceptibility to environmentally based disease. Journal of Toxicology and Environmental Health 40:289-308, 1993			
	A32	Gonzalez et al., Characterization of the common genetic defect in humans deficient in debrisoquine metabolism, Nature 331:442-446, 1988			
	A33	Gonzalez and Idle, Pharmacogenetic phenotyping and genotyping: Present status and future potential, Clin. Pharmacokin. 26:59-70, 1994.			
DBJ A34		Gonzalez and Gelboin, Role of human cytochromes P450 in the metabolic activation of chemical carcinogens and toxins, Drug, Metab. Rev. 26: 165-183, 1994			

Examiner Signature	/Diana B. Johannsen/	Date Considered	10/23/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

persons are required to respond to a collection of information unless it contains a valid OMB control Under the Paperwork

	Substitute of RULE	1129B/	PTO .		Complete if Known	
	INFORMATION DI	SCLO	SURE	Application Number	10/615,497	
	STATEMENT BY	APPLI	CANT	Filing Date	07/07/2003	
				First Named Inventor	Doug Hui Huang	
				Group Art Unit	1632	
	(use as many sheets	as ne	cessary)	Examiner Name		
Sheet	5	of	10	Attorney Docket Number	034827-1303	

7.7		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
DBJ	A35	Gonzalez, The role of carcinogen-metabolizing enzyme polymorphisms in cancer susceptibility, Reproduct. Toxicol. 11, 397-412, 1997.	
	A36	Guengerich et al., Role of human cytochrome P-450 IIE1 in the oxidation of many low molecular weight cancer suspects, Chem. Res. Toxicol. 4, 168-179, 1991	
	A37	Guidice et al., Evidence for CYP2D6 expression in human lung, Biochem Biophys Res Commun 241:79-85, 1997	
	A38	Hasler et al., Human cytochromes P450, Molecular Aspects of Medicine 20:1-137, 1999	
	A39	Heller, Principles of DNA separation with capillary electrophoresis, Electrophoresis 22:629-43, 2001	
	A40	Hersberger et al., Rapid detection of the CYP2D6*3, CYP2D6*4, and CYP2D6*6 alleles by tetra-primer PCR and of the CYP2D6*5 allele by multiplex long PCR, Clinical Chemistry 46:8, 1072-1077, 2000	
	A41	Hiemke and Hartter, Pharmacokinetics of selective serotonin reuptake inhibitors, Pharmacology & Therapeutics 85:11-28, 2000	
DBJ	A42	Hoffman et al., Organization and evolution of the cytochrome P450 CYP2A-2B-2F subfamily gene cluster on human chromosome, J. Molec. Evolut. 41, 894-900, 1995	

Examiner Signature	/Diana B. Johannsen/	Date Considered	10/23/2006
Oignature		Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

	Substitut PART	449B/	PTO		Complete if Known	
	INFORMATION			Application Number	10/615,497	
	STATEMENT 6	SY APPLI	CANT	Filing Date	07/07/2003	
				First Named Inventor	Doug Hui Huang	
				Group Art Unit	1632	
	(use as many she	ets as ne	cessary)	Examiner Name	·	
Sheet	6	of	10	Attorney Docket Number	034827-1303	

		NON PATENT LITERATURE DOCUMENTS		
Examiner Cite No.		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т ⁶	
DBJ	A43	Johansson et al., Inherited amplification of an active gene in the cytochrome P450 CYP2D locus as a cause of ultrarapid metabolism of debrisoquine, Proc Natl Acad Sci 90: 11825-11829, 1993		
	A44	Kagimoto et al., Multiple Mutations of the Human Cytochrome P450IID6 Gene (CYP2D6) in Poor Metabolizers of Debrisquine, J. Biol. Chem. 265:17209-17214, 1990		
	A45	Kalow, Pharmacogenetics in Biological Perspective, Pharmacological Reviews, 49:369-379, 1997.		
1,				
	A46	Kashuba ADM, et al., Quantification of intraindividual variability and the influence of menstrual cycle phase on CYP2D6 activity as measured by dextromethorphan phenotyping. <i>Pharmacogenetics</i> . (1998) 8:403-410		
	A47	Kellermann et al., Arylhydrocarbon hydroxylase and bronchogenic carcinoma, New Eng. J. Med. 289, 934-937, 1973		
	A48	Kroemer and Eichelbaum, "Molecular bases and clinical consequences of genetic cytochrome P450 2D6 polymorphism." Life Sci 56:2285-98, 1995		
V				
DBJ	A49	LeCluyse, Human hepatocyte culture systems for the in vitro evaluation of cytochrome P450 expression and regulation, European Journal of Pharmaceutical Sciences 13: 343-368, 2001		

Examiner Signature	/Diana B. Johannsen/	Date Considered	10/23/2006
-----------------------	----------------------	--------------------	------------

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Agos 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

	S. White Galls	orm 1449B	/PTO		Complete if Known			
	INFORMATIO	ON DISCLO	SURE	Application Number	10/615,497			
	STATEMENT	BY APPLI	ICANT	Filing Date	07/07/2003			
•				First Named Inventor	Doug Hui Huang			
				Group Art Unit	1632			
	(use as many s	heets as ne	ecessary)	Examiner Name				
Sheet	7	of	10	Attorney Docket Number	034827-1303			

	NON PATENT LITERATURE DOCUMENTS						
Examiner Cite No.		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	τ'				
DBJ	A50	Legrand-Andreoletti et al., Cytochrome P450 CYP2D6 gene polymorphism and lung cancer susceptibility in Caucasians, Pharmacogenetics 8:7-14, 1998					
		Lindblad-Toh et al., Large-scale discovery and genotyping of single-nucleotide polymorphisms in the mouse. Nature Genet 2000 Apr 024(4):381-6					
	A52	Linder et al., Pharmacogenetics: a laboratory tool for optimizing therapeutic efficiency, Clinical Chemistry 43:254-266, 1997					
	A53	Lovlie et al., Ultrarapid metabolizers of debrisoquine: characterization and PCR-based detection of alleles with duplication of the CYP2D6 gene, FEBS lett. 392:30-34, 1996					
	A54	Lu, Drug-metabolism research challenges in the new millennium, Drug Metabolism And Disposition, 26:12, 1217-1222, 1998					
	A55	Marez et al., Polymorphism of the cytochrome P450 CYP2D6 gene in a European population: characterization of 48 mutations and 53 alleles, their frequencies and evolution, Pharmacogenetics 7:193-202, 1997					
	A56	Meldrum, Automation for Genomics, Part Two: Sequencers, Microarrays, and Future Trends, Genome Research, 10:1288-1303, 2000					
DBJ	A57	Mitchelson, "The Application of capillary electrophoresis for DNA polymorphism analysis." Methods Mol Biol 162:3-26, 2001					

Examiner /Diana B. Johannsen/ Signature	Date Considered	10/23/2006
---	--------------------	------------

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Under the Paperway Reduction Acts

number.

Sheet

MARCHAN					
Substitute for form	1449B/PT	0		Complete if Known	
INFORMATION DIS	SCLOSU	RE	Application Number	10/615,497	
STATEMENT BY A	APPLICA	NT	Filing Date	07/07/2003	
			First Named Inventor	Doug Hui Huang	
			Group Art Unit	1632	
(use as many sheets	as neces	sary)	Examiner Name		
R	of 1	0	Attorney Docket Number	034827-1303	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials* Cite No.1 DBJ A58		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		Mogil, The genetic mediation of individual differences in sensitivity to pain and its inhibition, Proc. Natl. Acad. Sci. 96:7744-7751, 1999	
	A59	Nasu et al., Genetic analysis of CYP2C9 polymoprhism in a Japanese population, Pharmacogenetics 7: 405–409, 1997	
	A60	Nunoya et al., A new deleted allele in the human cytochrome P450 2A6 (CYP2A6) gene found in individuals showing poor metabolic capacity to coumarin and (+)-cis-3,5-dimethyl-2(3-pyridyl)thiazolidin-4-one hydrochloride (SM-12502), Pharmacogenetics 8, 239-249, 1998	
	A61	Oliver et al., Use of Single Nucleotide Polymorphisms (SNP) and Real-Time Polymerase Chain Reaction for Bone Marrow Engraftment Analysis, Journal of Molecular Diagnostics 2:202-208, 2000	
	A62	Rautio et al., Interindividual variation of coumarin- hydroxylation in healthy volunteers, Pharmacogenetics 2, 227-233, 1992	
	A63	Sabbagh et al., Genetic analysis of the cytochrome P450 CYP2D6 polymorphism in patients with systemic lupus erythematosus, Pharmacogenetics 8:191-4, 1998	
	A64	Schmitz et al., "Pharmacogenomics: implications for laboratory medicine." Clinica Chimica Acta 308:43-53, 2001	
DBJ	A65	Schur et al., Genotyping of cytochrome P450 2D6*3 and *4 mutations using conventional PCR, Clinca Chimica Acta 308, 25-31, 2001	

Examiner /Diana B. Johannsen/ Signature	Date Considered	10/23/2006
---	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Oocuments. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the senal number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁴Applicant is to place a check mark here if English language

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwolf Reduction Act of \$995, no persons are required to respond to a collection of information unless it contains a valid OMB control

	Substitute 40125	11 1449B	PTO	Complete if Known		
	INFORMATION	DISCLO	SURE .	Application Number	10/615,497	
	STATEMENT BY APPLICANT			Filing Date	07/07/2003	
				First Named Inventor	Doug Hui Huang	
				Group Art Unit	1632	
(use as many sheets as necessary)			cessary)	Examiner Name		
Sheet	9	of	10	Attorney Docket Number	034827-1303	

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			
DBJ	A66	Stephens et al., "Ethnic variation in the CYP2E1 gene: polymorphism analysis of 695 African-American, European-Americans and Taiwanese." Pharmacogenetics 4, 185-192, 1994			
	A67	Stimer et al., Pharmacogenetics: a new diagnostic tool in the management of antidepressive drug therapy, Clinical Chimica Acta 308:33-41, 2001			
	A68	Stubbins et al., Genetic analysis of the human cytochrome P450 CYP2C9 locus, Pharmacogenetics 6, 429-439, 1996			
	A69	Stuven et al., Rapid detection of CYP2D6 null alleles by long distance and multiplex polymerase chain reaction. Pharmacogenetics 6:417-421, 1996			
	A70	Sullivan-Klose et al., The role of the CYP2C9-Leu ³⁵⁹ allelic variant in the tolbutamide polymoprhism, Pharmacogenetics 6:341-349, 1996			
	A71	van der Weide et al., Cytochrome P450 enzyme system: Genetic polymorphisms and impact on clinical pharmacology, Ann Clin Biochem 36:722-729, 1999			
	A72	Wang et al., Detection of CYP2C9 polymoprhiism based on the polymerase chain reaction in Chinese, Pharmacogenetics, 5,37-42, 1995	<u>.</u>		
DBJ	A73	Ward et al., The activation of the biguanide antimalarial prguanil co-segregates with the mephenytoin oxidation polymoprhism – a panel study, Br. J. Clin. Pharmacol. 31, 689-692, 1991			

. Examiner Signature	/Diana B. Johannsen/	Date Considered	10/23/2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document, ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁹Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwolk Reduction Act of

of \$95, no persons are required to respond to a collection of Information unless it contains a valid OMB control

	Substitute 1449B/PTO			Complete if Known		
INFORMATION DISCLOSURE				Application Number	10/615,497	
	STATEMENT BY APPLICANT			Filing Date	07/07/2003	
				First Named Inventor	Doug Hui Huang	
				Group Art Unit	1632	
(use as many sheets as necessary)			cessary)	Examiner Name		
Sheet	10	of	10	Attorney Docket Number	034827-1303	

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶			
DBJ A74		Weber et al., "Pharmacogenetic Testing," Encyclopedia of Analytical Chemistry, Robert A. Myers editor, John Wiley & Sons Ltd., Chichester; Volume 2, 2000.				
	A75	Wilkinson, Cytochrome P4503A (CYP3A) metabolism: prediction of <i>in vivo</i> activity in humans, J Pharmacokinet Biopharm 24:475-90, 1996				
	A76	Wolf et al., Chapter 18. Cytochrome P450 CYP2D6, IARC Sci Publ 148:209-29, 1999				
A77		Yasar et al., Validation of methods for CYP2C9 genotyping: frequencies of mutant alleles in a Swedish population. Biochem Biophys Res Commun 254:628-31, 1999 (abstract).				

Examiner /Diana B. Johannsen/ Signature	Date Considered	10/23/2006
---	--------------------	------------

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.